

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Allowed: January 26, 2005

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Group Art Unit: 1615

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Examiner: Amy E. Pulliam

Filed: December 21, 1999

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U.S. Patent No.: 6,939,559

For: **PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA**

**SUBMISSION OF ART**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

For the possible benefit of anyone subsequently evaluating the scope and/or validity of the above-identified patent, it is requested that the document that is listed below (copy enclosed) be placed in the U.S. Patent and Trademark Office's file wrapper of the above-identified U.S. patent:

Abstract- "Non-oral administration of progesterone: experiences and possibilities of the transvaginal route", Schweiz Rundsch Med Prax, 1995 Feb. 1, 84(5): 127-33.

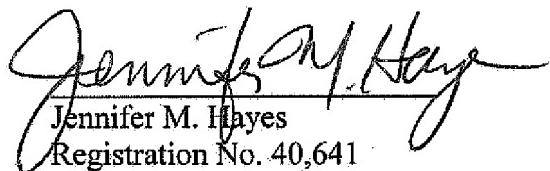
The undersigned has not reviewed the teachings of the above-listed document in detail and thus makes no representations concerning the relevancy or materiality of the above-listed document.

SUBMISSION OF ART  
U.S. Application No.: 09/446,276

Attorney Docket No.: Q57234

This is not an Information Disclosure Statement and no response from the U.S. Patent and Trademark Office is believed to be necessary, nor are any fees believed to be due.

Respectfully submitted,



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□ 1: *Schweiz Rundsch Med Prax* 1995 Feb 1;84 (5):127-33

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[Non-oral administration of progesterone: experiences and possibilities of the transvaginal route].

[Article in French]

de Ziegler D, Seidler L, Scharer E, Bouchard P

Service d'endocrinologie gynécologique, Clinique de Genolier.

Recent development of transdermal therapy permits application of estrogen, usually produced in the ovaries, in physiological dosage by means of continuous release from either an epidermal patch or dermal application of a gel. Transdermal therapy with progesterone, however is impossible due to poor dermal absorption and high dose requirements (release from corpora lutea: 25 mg/24 hours). Two other possibilities have been proposed. On one hand it is possible to apply norethisterone-acetate (NETA), another gestagen, epicutaneously. This mode of administration carries the same problems as oral application thus allowing for a dose reduction. On the other hand progesterone can be applied vaginally. This mode leads to significantly higher plasmatic concentrations of progesterone and has effects on the uterine mucosa similar to those in a normal cycle. This modality thus permits application of estradiol and progesterone in a physiological manner by a non oral route. It appears particularly interesting in patients at cardiovascular risk.

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Publication Types:

- Review
- Review, tutorial

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